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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/886,241	06/21/2001	Susana Salceda	DEX-0209	5811
26259	7590	08/11/2004		
LICATLA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053			EXAMINER HARRIS, ALANA M	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/886,241

Applicant(s)

SALCEDA ET AL.

Examiner

Alana M. Harris, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3 and 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/24/05
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Response to Arguments and Amendments

1. Claims 3 and 16 are pending.
Claims 4-7 have been cancelled.
Claim 3 has been amended.
Claims 3 and 16 are examined on the merits.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Rejection

Claim Rejections - 35 USC § 112

3. The rejection of claim 3 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for determining the levels of expression of SEQ ID NO: 4, does not reasonably provide enablement for determining the level of the gene itself is withdrawn in light of the claim amendment.
4. The rejection of claim 3 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for diagnosing the presence of breast cancer in a patient comprising determining levels of a breast specific polynucleotide designated as SEQ ID NO: 4 (or breast specific gene, BSG: sqmam042) in cells, tissue or bodily fluids in a patient and comparing the determined levels of a polynucleotide

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comprising SEQ ID NO: 4 or a polynucleotide encoding the same polypeptide in cells, tissue or bodily fluids from a normal human control, wherein a change in determined levels of a BSG polynucleotide comprising SEQ ID NO: 4 or a polynucleotide encoding the same polypeptide as SEQ ID NO: 4 in said patient versus normal human control is associated with presence of breast cancer, does not reasonably provide enablement for methods of diagnosing metastases, staging and monitoring changes in gastrointestinal cancer is withdrawn in light of the claim amendment. Claims 4-7 have been cancelled.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

5. Claims 3 and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for diagnosing the presence of breast cancer in a patient comprising determining levels of a breast specific polynucleotide designated as SEQ ID NO: 4 in cells, tissue or bodily fluids in a patient and comparing the determined levels of a polynucleotide comprising SEQ ID NO: 4, wherein a change in determined levels of polynucleotide of SEQ ID NO: 4 in said patient versus normal human control is associated with presence of breast cancer, does not reasonably provide enablement for a polynucleotide encoding a polypeptide encoded by SEQ ID NO: 4 for the presence of any cancer.

Applicants' specification does not evidence the intended use of degenerate sequences of SEQ ID NO: 4, which is embraced by the claim language. The record has clearly established that SEQ ID NO: 4 is a unique or molecular marker for breast

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cancer. However, there is insufficient evidence provided to support the use of the degenerate sequences in a diagnostic method for any cancer and specifically breast cancer. Furthermore, Applicants have not provided any disclosure enabling the use of degenerate coding sequences of SEQ ID NO: 4. There is no disclosure designating what changes to the coding sequences could be tolerated enabling one of ordinary skill in the art to make and use the said sequences in any cancer detection method. The experimental design presented in the specification lacks information regarding the applicability of degenerate coding sequences of SEQ ID NO: 4 in detection methods relative to cancer. Applicants have not set forth any supporting evidence that suggests that degenerate sequences of SEQ ID NO: 4 is a unique tumor or molecular marker for cancer. Attached to the instant office action is a sequence alignment between Applicants' SEQ ID NO: 4 and sequence that is from a family of genes encoding PCK-dependent protein phosphatase 1 inhibitors. This degenerate sequence of SEQ ID NO: 4 would more than likely not be useful in the detection of cancer in a patient. It is not reasonable to conclude that degenerate sequences of SEQ ID NO: 4 would be effective in yielding a definitive detection of cancer disorders with distinguishing pathologies.

Based on the analysis and the teachings presented above the claims do not read on the entire breadth of the claim. There is insufficient support in the specification for the enablement of the broadly claimed invention.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The examiner works a flexible schedule, however she can normally be reached between the hours of 6:30 am to 5:30 pm with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alana M. Harris, Ph.D.

09 August 2004



ALANA M. HARRIS, PH.D.

PRIMARY EXAMINER

8/9/2004